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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,217	01/16/2004	Masaaki Nomura	159-83	5718

23117 7590 01/13/2005  
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Applicati n N .

10/758,217

Applicant(s)

NOMURA ET AL.

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01/16/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. 07/23/04.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of preliminary amendment (amendment to the claims and specification) filed 01/16/04, IDS filed 01/16/04 and correction submitted 04/29/04 and response to restriction requirement filed 08/20/04. Claims 11-25 are pending.

#### ***Information Disclosure Statement***

1. The information disclosure statement filed 04/29/04 has been considered in part as it relates to the US Patent documents. However, copies of the foreign patent documents and the non-patent literature documents are not provided. This observation was also made in the previous action of the parent application number 10/062,720. Examiner respectfully requests applicants to submit copies of the foreign patents and non-patent literature cited on the Form PTO-1449.

#### ***Election/Restrictions***

Examiner acknowledges applicants' election of group I, claims 11-20 without traverse in the response/election filed 08/20/04.

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11-13 and 15-19 rejected under 35 U.S.C. 102(b) as being anticipated by Girjavallabhan et al. (US 4,411,906).

Girjavallabhan discloses a pharmaceutical composition comprising effective amount of penem and a pharmaceutically acceptable carrier or coating (column 2, lines 32-36). The penem used in the composition of Girjavallabhan is the (5R, 6S, 8R)-6-(1-hydroxyethyl)-2-(fluoroalkylthio)-penem-3-carboxylic acid (abstract and column 1, lines 5 and 6), which is the recited penem antibiotic, also known as Faropenem. Girjavallabhan's composition may also contain other compatible antibacterial agents and/or enzyme inhibitors (column 2, lines 36-39). Girjavallabhan discloses administering the composition to treat bacterial infection in warm-blooded animals (column 2, lines 40-44); the administration is through oral administration in the form of tablets, capsules, elixirs and the composition can also be administered topically in ointments that can be both hydrophilic and hydrophobic or aqueous or non-aqueous lotions of the emulsion type and in the form of creams (column 2, lines 47-68). The ointment has hydrophobic base carrier. The composition of further contains cornstarch (thickener) and magnesium stearate as in tablet and capsule formulation (examples 3 and 4), and hydroxypropyl cellulose (thickener) and polyethylene glycol as in topical formulation (example 5). Since the prior art also topically treats bacterial infection, instant claim 15 directed to treating infectious disease of the dermis/dermatology reads on a topical treatment of bacterial infection. Polyethylene glycol is hydrophilic. Hydroxypropylcellulose is recited as a hydrophilic polymer is dependent claim 18. The teachings of Girjavallabhan meet the limitations of the claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1615

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 14 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girjavallabhan et al. (US 4,411,906) in view of Kari (US 5,654,451).

Girjavallabhan discloses topically treating bacterial infection with a composition that comprises penem antibiotic as described above. Regarding claim 14, Girjavallabhan discloses 2.5% drug by weight of the total topical formulation (example 5) and the penem antibiotic described in the Girjavallabhan art is a carboxylate. However, the antibiotic can also exist in the anhydride form and the anhydride form of the penem antibiotic in a composition that is used to treat infection disease is not inventive over the carboxylate form since both forms are sources for the drug. Girjavallabhan fails to treat periodontal disease. But Kari discloses topical administration of composition that comprises antibiotics such as penem antibiotic for treating periodontal disease (column 19, lines 13-19 and column 30, lines 39-50). The composition of Kari contains compounds other than the penem antibiotic. However, it is noted that instant claim 11 uses a composition that comprises a penem antibiotic and because the claimed composition uses the comprising language, the instant composition does not exclude the other compound in the Kari art. And Kari is relied upon for using a composition comprising penem antibiotic for treating periodontal disease. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Girjavallabhan to treat bacterial infection by topical application. One having of ordinary skill in the art would have been motivated to use the composition of Girjavallabhan to treat periodontal disease according to the teaching of Kari with the expectation that the composition of the prior art would be effective in treating periodontal disease.

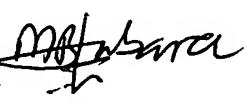
Art Unit: 1615

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara   
Patent Examiner  
Tech. Center 1600